Cognitive
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Research Institute
Post Office Box 4029, Menlo Park, California, 94026 USA Phone: 650-321-CERI Fax: 650-323-3864

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5 May 1999

Dockets Management Branch (HFA-305), Docket #98-N-1265
Food & Drug Administration
5600 Fishers Lane, Room 1061
Rockville, Maryland
20857 USA

Attn: Dockets manager,

Arbitrary restrictions on amount of compounded medications prescribed by state-licensed practitioners, prepared by state-licensed compounded pharmacies and delivered to consumers in other states is inappropriate for several reasons.

First, there is no public health benefit to be obtained. Any presumption by FDA that volume of interstate sales is in any way directly associated with either poor quality product or a real consumer risk is unreasonable on its face and should fail the "blush" test when challenged in Federal Court. Any such argument should be supported by specific evidence that should meet both scientific and judicial standards. As a scientist familiar with some compounding pharmacy products in interstate commerce, I doubt that the FDA is prepared to meet such an evidentiary burden.

Second, the phrase "inordinate amount" is both arbitrary and subjective and therefore open to abuse. Such potential for abuse is unacceptable due to the FDA's stated and acknowledged policy that the practice of compounding is illegal and should cease. Such politically motivated policy is in direct conflict with Constitutional provisions guaranteeing sovereignty to the many states, which has been judged to include the regulation of medicine and pharmacy. This policy is also in direct conflict with the public-health mission of the FDA.

Third, it is obvious that the FDA's drug-marketing approval process is entirely inadequate to meeting the needs of patient with special, unusual or atypical medication needs. Compounding pharmacies have historically met those needs, and are doing so now to ever greater degree as the advancing state-of-the-art in medicine is recognizing the importance of subtle and synergistic interactions between patients and drugs, vehicles, preservatives and routes of administration and variable drug metabolism. Since medicine and compounding are arts as well as sciences, the decision as to which compounder is best able to provide the requisite product and service must remain entirely in the hands of state-licensed physicians *who are the only agents capable of determining the unique clinical response of the patient with special needs.* Thus, the draft Memorandum of Understanding (MOU) illegally interferes with both the practice of compounding and the practice of medicine.

Fourth, in practice, compounding pharmacists develop specialty knowledge and experience which 1) gives them a competitive advantage over other pharmacists without such knowledge and experience, and 2) makes them better able to meet the needs of special-need patients. Your "inordinate amount" restriction is likely to specifically target such pharmacists who have

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national reputations in their specific area of expertise and thereby ship their specialty compounds throughout the many states. While it may be true that the compounding pharmacist might be able to establish separate pharmacies in every state to avoid this arbitrary restriction on interstate sales, this would be an unreasonable economic burden that conflicts with Constitutional provisions guaranteeing US citizens the right to earn a living unburdened by unreasonable laws and regulations. Of course, preventing state-licensed physicians from accessing superior products compounded in other states would have an entirely negative impact on public health and would directly contravene the public-heath mission of the FDA. It would also be an illegal Federal intrusion into the Constitutionally state-reserved power to regulate medical practice.

I strongly oppose the draft M.O.U. because it fails to regulate the practice of compounding in ways that are Constitutionally authorized, and instead substitutes a arbitrary quantitative standard that is not only illegal, but easy for politically motivated regulators to abuse with the likely consequence of undermining both public health and the US Constitution. It is not only bad public policy, it also reflects badly on the moral and ethical values of present FDA personnel who would advance such a dysfunctional and counterproductive policy. No compounded medication prescribed by a licensed practitioner should be denied interstate access without clear and specific evidence of public health hazard. It is my sincere belief that volume of sales is in no way associated with any hazard.

Sincerely,

Steven Wm. Fowkes
Executive Director

P.O.Box4029
Menlo Park, California
94026-4029 USA

Address Service Requested

SAN FRANCISCO CA 941
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